

REMARKS

Claims 1-19 stand rejected. Applicant has amended claims 14 through 19 to correct typographical errors in the claim numbering and to correct claim dependencies. Applicant respectfully traverses the Examiner's rejection of the claims in view of the remarks below.

Claims Objections

Claims 14 through 19 were objected to as improperly numbered. Claims 14 through 19 have been amended to correct the claim numbering and the claim dependencies.

Double Patenting

Claims 1, 6, 7, 10, 11, 13, 18, and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, and 11 of U.S. Patent No. 6,652,734. Enclosed herewith is a terminal disclaimer. Accordingly, Applicant respectfully requests withdrawal of this rejection.

Claim Rejection – 35 U.S.C. §112

Claims 13 through 17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 13 is rejected because 3-mercaptopropanoic acid is misspelled. Applicant respectfully disagrees, “3-mercaptopropanoic acid” and “3-meraptopropionic acid” are synonyms. Both terms are understood by one skilled in the art.

Claim 14, which originally depended from claim 12, is rejected as lacking antecedent basis. Claim 14 has been amended to depend from claim 13.

Claim Rejections – 35 U.S.C. §103

Claims 1-7, 10-13, 18, and 19 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Allen et al. (“Allen”) (J. Electroanal. Chem., 178 (1984), pp. 69-86) in view of Maley et al. (“Maley”) (U.S. Patent No. 5,529,676). With respect to claim 1, the rejection states that Allen discloses a metal electrode and numerous different sulfur-containing moieties for

coating. However, the Examiner admits that Allen does not disclose overcoating the coating with a surfactant. Maley is cited to teach treatment of a coated electrode with a surfactant.

Applicant respectfully traverses the rejection.

The Allen reference discloses research into the promotion of horse heart cytochrome *c* electrochemistry on a gold electrode. Fifty compounds were deposited on electrodes and tested as surface modifiers for the promotion of cytochrome *c* electrochemistry. Several of the groups were found to be useful. Allen does not disclose the use of an overcoating of any kind and one of ordinary skill in the art would have no motivation to add an overcoating to the compounds deposited on the electrodes of Allen.

Maley discloses an electrochemical sensor for the analysis of blood samples, and in particular, the measurement of glucose concentration. To reduce the affect of interfering substances, Maley positions a semi-permeable membrane on the working electrode. This membrane permits the passage of glucose, lactate, and/or oxygen.

Maley discloses that one difficulty with the membrane is that during dry storage of the sensors, the membranes become increasingly more difficult to wetup. Maley suggests that residual water and other solvents, initially present in the membrane after casting, evaporate during storage and cause coalescence of silicone agglomerates. This tightening of the membrane structure can decrease the sensitivity and increase the response time of the sensor toward glucose. To resolve this issue, the sensors are post-treated to prevent the membrane from aging during dry storage, for example, by preventing the membranes from fully drying with humidification, or treatment with a high boiling point, water soluble, hydrophilic polymer liquid antidrying agent. One agent is a surfactant or polyethylene glycol.

Maley also discloses mixing a surfactant with a platinized activated carbon material. This embodiment of Maley is not an overcoating.

The Examiner has failed to present a *prima facie* case of obviousness for the combination of Allen and Maley. The Maley reference is directed to a different device, used in a different way, for the analysis of a different analyte. The surfactants in Maley are used to as a treatment to prevent *a membrane* from aging during dry storage and as *an additive* for incorporation in a platinized activated carbon material. Accordingly, the teachings of Maley are not applicable to the Allen reference.

Allen is concerned with the electrochemistry of cytochrome *c*, while Maley is directed toward a glucose sensor having a membrane. The suggestion in Maley to apply a surfactant to a membrane to prevent *the membrane* from drying out, does not provide any motivation to apply a surfactant to a device lacking a membrane (i.e., the device of Allen). The application of a surfactant would provide no benefit to the electrode of Allen and one of ordinary skill in the art would thus have no reason to apply the surfactant of Maley to Allen.

Moreover, since Maley's teaches that the application of a surfactant assists with *glucose* monitoring, and the membrane is adapted for use with whole blood, there is no reasonable expectation of success. The membrane and the difficulties of membrane aging, according to Maley, are analyte specific. As stated by Maley “[t]his tightening of the membrane structure can decrease the sensitivity and increase the response time of the sensor toward *glucose*.[”] (emphasis added) Accordingly, one skill in the art would have not reason to believe that the teachings of Maley would improve the electrode of Allen and assist with the promotion of cytochrome *c* electrochemistry.

As an attempt to find motivation for adding a portion of Maley to Allen, the Examiner points to col. 30, line 56 through col. 31, line 8 of Maley. In this section of the Maley reference it is disclosed that a surfactant can be *incorporated* in the platinized activated carbon (PAC) material. However, Maley teaches that the surfactant is incorporated in the PAC rather than applied in an *overcoating* to a coating. The choice of language, i.e., incorporating, is specific and requires the surfactant to be mixed with the PAC layer. Moreover, the PAC layer is not applied on top of another coating, instead it is applied to the electrode. Accordingly, the portion

of Maley cited by the Examiner does not relate to an “overcoating.” In addition, Maley teaches that the surfactant should be added to platinized activated carbon to assist with glucose analysis, not to a sulfur containing moiety for the promotion of cytochrome *c* electrochemistry.

One of ordinary skill in the art would thus have no reason to believe that the addition of a surfactant, as disclosed in Maley, would assist with the promotion of cytochrome *c* electrochemistry as taught in Allen. The only basis for an obviousness type rejection based on the combination of Allen and Maley would be improper hindsight gleamed from Applicant’s own specification. Accordingly, Applicant respectfully requests withdrawal of the rejection.

The rejection based on Schlerich in view of Maley

Claims 1, 2, and 6 – 19 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Schlereth et al. (“Schlereth”) (Electroanalysis 1995, 7 (1), pp. 46-54) in view of Maley. The rejection states that Schlerich discloses a coated metal electrode where the metal electrode comprises a coating of a sulfur containing moiety comprising cysteine. However, the Examiner admits that Schlerich does not disclose the use of an overcoating of a surfactant and cites Maley to remedy the deficiencies of Schlereth.

Applicant respectfully traverses the rejection.

As discussed above, the combination of Allen and Maley fails to render Applicant’s claims obvious. Schlereth, which is cited to teach a sulfur containing moiety comprising cystine, does not disclose an overcoating and cannot make-up for the deficiencies of Maley. Schlereth discloses surface modified electrodes (SME) able to catalyze the oxidation of NADH. As part of the surface modification, amino-containing sulfur compounds, cystamine, and cysteine were used. The electrocatalytic oxidation of NADH at different mediator-SMEs was then monitored by cyclic voltammetry.

One of ordinary skill in the art would have no motivation to apply the teachings of Maley, which discloses a blood glucose sensor with a membrane, to the Schlereth reference. The

Maley reference discloses a different device, having a different structure, adapted to investigate a different analyte.

Moreover, even if these references could be combined, the combination would fail to teach the limitations of Applicant's claims. As discussed above, Maley does not disclose applying an overcoating of a surfactant to a coating comprising a sulfur containing moiety. Instead, a surfactant is applied to a membrane or incorporated into a platinized activated carbon material. In addition, even if a surfactant were added to the SME of Schlereth, there is no reasonable expectation of success. Oxidation of NADH is a much different chemical process from the detection and analysis of glucose. If a surfactant were added, it is unclear how the surfactant would effect the device of Schlereth. Accordingly, Applicant believes the combination of Allen, Maley, and Schlereth is improper and respectfully requests withdrawal of the rejection.

Applicant believes that independent claims 1, 18, and 19 distinguish over the cited prior art and that the dependent claims are allowable at least because they depend from an allowable base claims. Applicant respectfully requests withdrawal of all the outstanding rejections.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. However, should any outstanding issues remain, Applicant asks that the Examiner please contact the undersigned Attorney for Applicant.

Dated: July 11, 2005

Respectfully submitted,

By 
Kevin Cronin

Registration No.: 47,203
NUTTER McCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
(617) 439-2194
(617) 310-9194
Attorneys for Applicant

1436936.1